

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY; )  
SANTA FE NATURAL TOBACCO )  
COMPANY, INC.; ITG BRANDS, LLC; )  
LIGGETT GROUP LLC; NEOCOM, INC.; )  
RANGILA ENTERPRISES INC.; RANGILA )  
LLC; SAHIL ISMAIL, INC.; and IS LIKE )  
YOU INC.; )  
Plaintiffs, )  
v. )  
UNITED STATES FOOD AND DRUG ) CIVIL ACTION NO. 6:20-cv-00176  
ADMINISTRATION; )  
UNITED STATES DEPARTMENT OF )  
HEALTH AND HUMAN SERVICES; )  
JANET WOODCOCK, )  
in her official capacity as Acting Commissioner )  
of the United States Food and Drug )  
Administration; and )  
XAVIER BECERRA, )  
in his official capacity as Secretary of the United )  
States Department of Health and Human )  
Services; )  
Defendants. )

**PLAINTIFFS' THIRD MOTION TO EXTEND  
POSTPONEMENT OF RULE'S EFFECTIVE DATE**

Plaintiffs respectfully request that the Court grant a third 90-day extension of the initial 120-day postponement of the Rule's effective date, without prejudice to Plaintiffs' ability to seek additional relief if it becomes necessary.<sup>1</sup> In support of this request, Plaintiffs state as follows:

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<sup>1</sup> A former Defendant—Norris Cochran—has left his official position. Accordingly, this Motion is directed to his successor, Xavier Becerra, along with the three other defendants. Although

1. On May 6, 2020, Plaintiffs and Defendants filed a joint motion requesting that the Court postpone for 120 days the effective date of a Final Rule issued by the Food and Drug Administration (“FDA”), which would require the use of eleven new graphic warnings on cigarette packages and advertisements, *see Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) (“the Rule”). *See* Joint Mot., ECF No. 30, ¶¶ 1, 4, 7 (May 6, 2020). Defendants stipulated that, “[i]n light of the disruptive effects of the global outbreak of COVID-19 on both the regulated community affected by the Rule and on FDA, . . . justice require[d] a 120-day postponement of the Rule’s effective date, from June 18, 2021, to October 16, 2021.” *See id.* ¶ 4. Plaintiffs explained that the Rule would cause irreparable harm, including substantial compliance costs for the Manufacturer Plaintiffs. *See id.* ¶¶ 5–6. Plaintiffs further noted that they would need to seek expedited relief from the Court if the joint motion were not granted. *See id.* ¶ 5.

2. On May 8, 2020, the Court granted the parties’ joint motion. *See* Order, ECF No. 33 (May 8, 2020) (“Postponement Order”). The Court agreed that Plaintiffs would suffer “irreparable injury absent postponement of the rule’s effective date” because they “would face imminent compliance costs” and “those costs would not be reimbursed by the government if plaintiffs prevail[ed] on the merits.” *See id.* at 1–2. The Court thus postponed the Rule’s effective date for 120 days—from June 18, 2021, to October 16, 2021—and set forth a briefing schedule to facilitate an orderly and efficient resolution of this case. *See id.* at 1–4.

3. The parties then proceeded to file merits briefs in accordance with the schedule in the Court’s May 8, 2020 order. *See, e.g.*, Pls.’ Mot. for Summ. J. and a Prelim. Inj., ECF No. 34 (May 15, 2020); Defs.’ Combined Cross-Mot. for Summ. J. and Opp. to Pls.’ Mot., ECF No. 37 (July 2, 2020).

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Defendants have not filed a substitution notice relating to Xavier Becerra, such substitution occurs automatically under the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 25(d) (“An action does not abate when a public officer who is a party in an official capacity . . . ceases to hold office while the action is pending. The officer’s successor is automatically substituted as a party. Later proceedings should be in the substituted party’s name . . . . The court may order substitution at any time, but the absence of such an order does not affect the substitution.”).

In addition, Defendants filed a motion to dismiss for improper venue. Defs.' Mot. to Dismiss, ECF No. 36 (July 2, 2020). These motions remain pending before the Court.

4. On November 23, 2020, Plaintiffs filed a motion seeking a 90-day extension of the 120-day postponement of the Rule's effective date. *See* Pls.' Mot. to Extend Postponement of Rule's Effective Date, ECF No. 76 (Nov. 23, 2020). Plaintiffs explained that "199 days ha[d] elapsed since the Court postponed the Rule's effective date, and the Manufacturer Plaintiffs [were again] . . . facing the same imminent compliance costs that the original postponement was designed to address." *See id.* ¶ 4. Specifically, Plaintiffs noted that the Manufacturer Plaintiffs would have to redesign packaging, modify the printing process, purchase and engrave printing cylinders, print compliant packages, and redesign, modify, and replace point-of-sale advertisements at hundreds of thousands of retailers. *See id.* ¶ 4(a)–(d). Plaintiffs further explained that these steps would cost millions of dollars and thousands of employee hours, which would be unrecoverable if Plaintiffs prevailed, and that the balance of equities strongly favored granting a stay. *See id.* ¶¶ 4–6. Defendants opposed the motion. *See* Defs.' Opp. to Mot. to Extend Postponement of Rule's Effective Date, ECF No. 79 (Nov. 25, 2020).

5. Based on the "equitable reasons given in plaintiffs' motion" and "the reasons stated in the court's [previous] order . . . postponing the effective date of the challenged rule," the Court granted Plaintiffs' motion for an extension of the original postponement. *See* Order, ECF No. 80 (Dec. 2, 2020) ("Extension Order"). Accordingly, the Court postponed the Rule's effective date and related requirements for "an additional 90 days, until January 14, 2022." *Id.* at 1 ("The court **orders** that the effective date of the rule is postponed for an additional 90 days, until January 14, 2022. Any obligation to comply with the Tobacco Control Act's warning requirements, [1]5 U.S.C. § 1333(a)(1) and (b)(1), and the additional requirements in 21 U.S.C. §§ 387c(a)(2) and 387t(a), is also postponed for an additional 90 days, as is any other obligation to comply with a deadline tied to the effective date of the rule.").

6. On February 26, 2021, Plaintiffs filed a motion seeking a second 90-day extension of the 120-day postponement of the Rule's effective date. *See* Pls.' Second Mot. to Extend Postponement of Rule's Effective Date, ECF No. 86 (Feb. 26, 2021). Plaintiffs explained that the "Manufacturer

Plaintiffs [were] once again on the threshold of incurring the same irreparable and imminent compliance costs” that Plaintiffs had previously identified. *Id.* ¶ 7. Defendants opposed the motion. *See* Defs.’ Opp. to Pls.’ Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 88 (Mar. 1, 2020).

7. In light of the “equitable reasons given in plaintiffs’ motion for an extension” and “the reasons stated in the court’s [previous] order . . . postponing the effective date of the challenged rule,” the Court granted Plaintiffs’ motion for a second extension of the original postponement. *See* Order, ECF No. 89 (Mar. 2, 2021) (“Second Extension Order”). Accordingly, the Court postponed the Rule’s effective date and related requirements for “an additional 90 days, until April 14, 2022.” *Id.* at 1 (“The court **orders** that the effective date of the rule is postponed for an additional 90 days, until April 14, 2022. Any obligation to comply with the Tobacco Control Act’s warning requirements, 5 U.S.C. § 1333(a)(1) and (b)(1), and the additional requirements in 21 U.S.C. §§ 387c(a)(2) and 387t(a), is also postponed for an additional 90 days, as is any other obligation to comply with a deadline tied to the effective date of the rule.”).

8. Eighty days have passed since this Court’s most recent order granting a 90-day extension. The Manufacturer Plaintiffs are once again on the verge of incurring the same irreparable and imminent compliance costs that were identified in the previous joint motion for a stay, the first and second motions to extend postponement of Rule’s effective date, and the merits briefs and supporting declarations, and that the previous postponement orders were designed to address. *See* Joint Mot. ¶¶ 5–6; Pls.’ Mot. to Extend Postponement ¶¶ 4–5; Pls.’ Second Mot. to Extend Postponement ¶ 7; Pls.’ Mot. for Summ. J. and Prelim. Inj. at 59–64; Decl. of Lamar W. Huckabee, ECF No. 34-5 (May 15, 2020) (attached as Exhibit A); Decl. of Kim Reed, ECF No. 34-6 (May 15, 2020) (attached as Exhibit B); Decl. of Francis G. Wall, ECF No. 34-7 (May 15, 2020) (attached as Exhibit C); Pls.’ Combined Reply and Resp., ECF No. 59, at 39–40. The legal analysis and balance of the equities are indistinguishable from the previous extension motions, which this Court granted on December 2, 2020, and March 2, 2021. *See* Extension Order at 1; Pls.’ Mot. to Extend Postponement

¶¶ 5–6; Second Extension Order at 1; Pls.’ Second Mot. to Extend Postponement ¶¶ 6–7. Another extension is therefore warranted under 5 U.S.C. § 705.

9. Accordingly, Plaintiffs request an additional 90-day extension of the postponement of the Rule’s effective date and related requirements, from April 14, 2022, to July 13, 2022. Plaintiffs further request that the additional 90-day extension be granted without prejudice to Plaintiffs’ right to move for additional relief at a later date, including another motion requesting a further postponement of the Rule’s effective date, and without prejudice to Plaintiffs’ pending motions.

10. As detailed in the certificate of conference, counsel for Plaintiffs and Defendants have discussed Plaintiffs’ intention to file this motion, and Defendants’ counsel has informed Plaintiffs’ counsel that Defendants oppose this motion for substantially the same reasons set forth in Defendants’ oppositions to Plaintiffs’ previous motions for a 90-day extension.

Respectfully submitted,

/s/ Ryan J. Watson

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 21, 2021, a true and correct copy of the foregoing was electronically filed with the clerk of court for the U.S. District Court for the Eastern District of Texas, using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

*/s/ Ryan J. Watson*

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**CERTIFICATE OF CONFERENCE**

I hereby certify, pursuant to Local Rule CV-7(i), that (1) I complied with the meet and confer requirement in Local Rule CV-7(h), and (2) this motion is opposed.

I have conducted the personal conference required by Local Rule CV-7(i). Specifically, I emailed Defendants' counsel on May 13, 2021, to inform them of Plaintiffs' intention to seek an additional postponement of 90 days. The next day, on May 14, 2021, I, along with Alex Potapov, had a telephone conference with Stephen M. Pezzi to discuss Plaintiffs' request for an additional postponement of the Rule's effective date, as well as Defendants' position with respect to that motion. After a collegial discussion where both sides discussed the issues in good faith, Defendants' counsel stated that Defendants oppose the motion for substantially the same reasons that Defendants opposed Plaintiffs' first and second motions to extend the postponement. The conference participants then concluded that the discussion had ended in an impasse, leaving an open issue for the Court to resolve.

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